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CaridianBCT, Inc.
Mail Stop: 810 1F2
10811 WEST COLLINS AVE
LAKEWOOD, CO 80215

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BRUCE W. GIBBS

Appeal 2008-005479
Application 09/672,519
Technology Center 3700

Decided: September 10, 2009

Before DONALD E. ADAMS, ERIC GRIMES, and
LORA M. GREEN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a preconnected disposable for red blood cell collection. The Examiner has rejected the claims as anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm in part.

STATEMENT OF THE CASE

The Specification discloses a red blood cell (RBC) collection system comprising, among other components, an "RBC collection tubing assembly 950" (Spec. 15:16-17). The Specification's Figure 2A is reproduced below with unneeded reference numerals omitted:

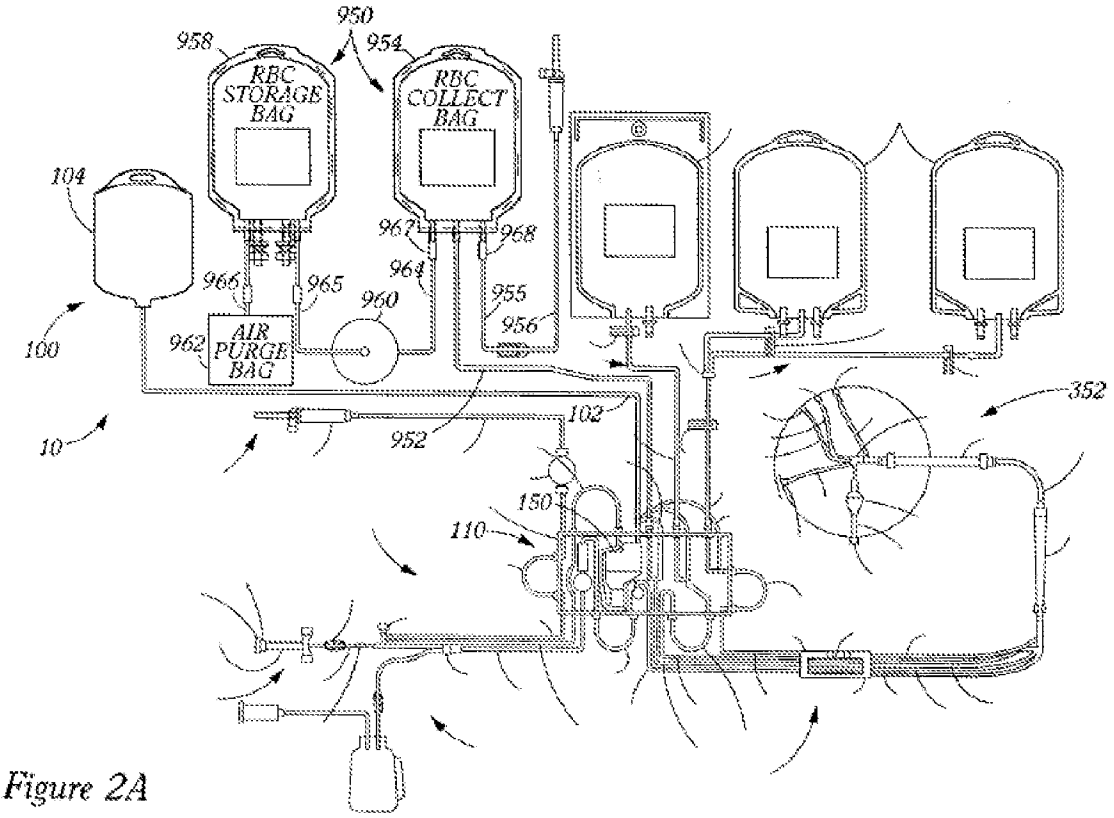

Figure 2A

The figure shows "an extracorporeal tubing circuit, cassette assembly, and filter/storage bag assembly" (*id.* at 15: 16-17). The elements shown in Figure 2A include "RBC collection tubing assembly 950 [which] includes . . . an RBC collection reservoir or bag 954, an RBC filtration/storage sub-assembly including an RBC storage reservoir or bag 958, an RBC leukoreduction filter 960 and an air removal bag 962. A sterile barrier filter/drip spike assembly 956 may also be included." (*Id.* at 15: 16-20.)

Claims 1-6 are pending and on appeal. Claims 1-3 are representative and read as follows:

1. A preconnected disposable for an apheresis system for separating blood into at least one component for collection, said disposable comprising

a blood removal/return assembly for removing blood and returning any uncollected components to the donor;

a cassette assembly interconnected to said blood removal/return assembly, said cassette assembly comprises integral fluid passageways for the passage of blood and blood components;

a blood processing vessel interconnected to said cassette assembly for separating blood received from the donor into components; and

a red blood cell collection assembly comprising

a red blood cell collection bag interconnected to said cassette assembly for receiving separated red blood cells when red blood cells are the component to be collected;

a leukoreduction filter interconnected to said red blood cell collection bag; and

a red blood cell storage bag interconnected to said leukoreduction filter.

2. The preconnected disposable of claim 1 further comprising an air removal bag interconnected to said red blood cell storage bag for receiving air from said red blood cell storage bag.

3. The preconnected disposable of claim 1 further comprising first tubing interconnected between said leukoreduction filter and said red blood cell collection bag; and

a frangible connector in said first tubing for allowing said first tubing to be opened for the passage of red blood cells through said first tubing.

The claims stand rejected as follows:

- Claims 1, 5, and 6 under 35 U.S.C. § 102(b) as anticipated by Keller[1] (Answer 3);
- Claim 2 as obvious in view of Keller (Answer 5); and
- Claims 3 and 4 as obvious in view of Keller and Minshall[2] (Answer 6).

ANTICIPATION

Issue

The Examiner has rejected claims 1, 5, and 6 as anticipated by Keller. The Examiner finds that claim 1 is anticipated by Keller's embodiment that includes a leukoreduction filter: "In order to carry out the leukocyte filtration, one would have to connect the filter to the tubing and a storage bag resulting in a preconnected or interconnected leukoreduction filter. Regardless of when the connection of the filter is made, the filter is preconnected between the collection bag and the storage bag." (Answer 8.)

Appellant contends that Keller does not expressly or inherently disclose a leukoreduction filter as a *preconnected* part of its product, as required by claim 1 (Appeal Br. 3-5). Appellant contends that "[b]y definition, . . . a preconnected filter is always connected before, earlier than, or prior to the use of the disposable in an apheresis procedure" (Reply Br. 5).

The issue with respect to this rejection is: Did the Examiner err in finding that claim 1 reads on an embodiment disclosed by Keller?

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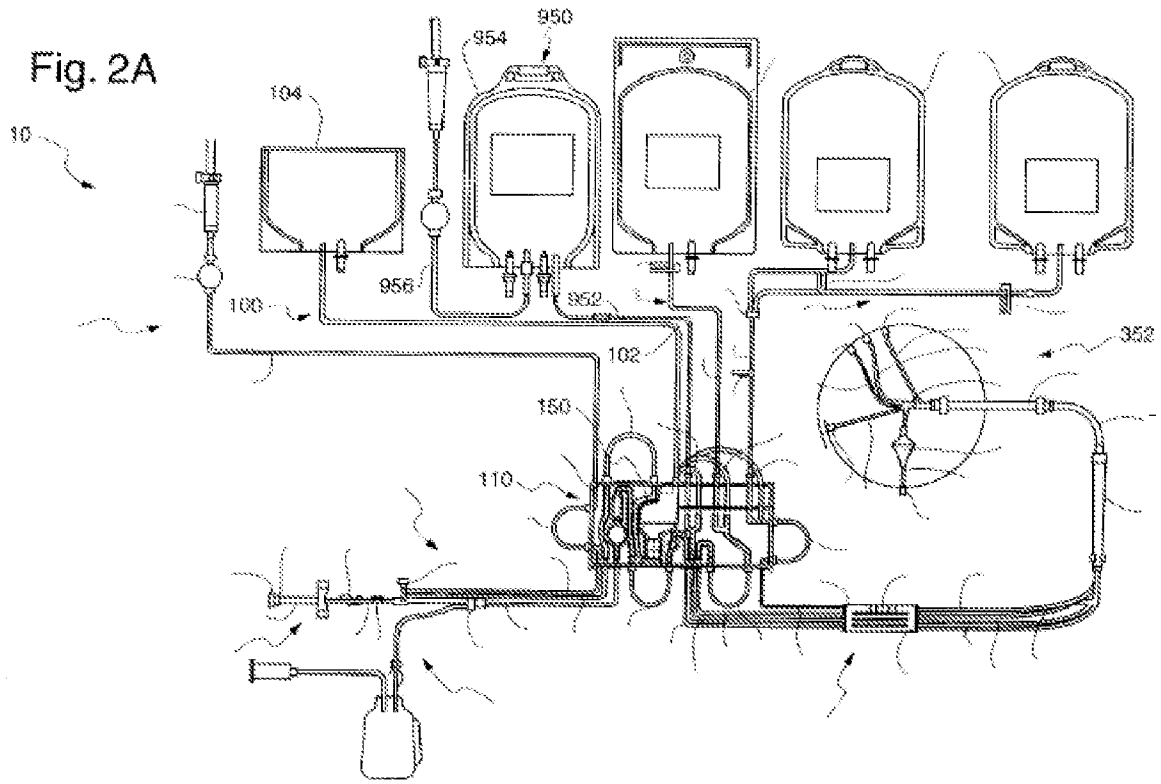
[1] Keller, US 6,200,287 B1, issued Mar. 13, 2001.
[2] Minshall, US 5,009,654, issued Apr. 23, 1991.

Findings of Fact

1. Keller discloses "methods and apparatus which may be incorporated into an apheresis system (e.g., blood component collection, therapeutic)" (Keller, col. 1, ll. 8-10).

2. Keller's Figure 2A is reproduced below, with unneeded reference numerals omitted.



The figure shows an extracorporeal tubing circuit and cassette assembly (*id.* at col. 13, ll. 28-29).

3. Keller discloses that blood flows from a patient (not shown in Figure 2A) "through the extracorporeal tubing circuit 10, and into the rotating blood processing vessel 352," where it is separated into its components (*id.* at col. 16, ll. 31-33).

4. Keller discloses that "[b]lood components which are not being retained for collection or for therapeutic treatment . . . are also removed from the blood processing vessel 352 and returned to the donor/patient 4 via the extracorporeal tubing circuit 10" (*id.* at col. 16, ll. 37-42).

5. Keller discloses that "RBC collection tubing assembly 950 includes RBC collector tubing 952, an RBC collection reservoir, or bag 954, and sterile barrier filter/drip spike assembly 956" (*id.* at col. 19, ll. 17-19).

6. Keller discloses that "[v]ent bag tubing assembly 100 is also interconnected to the top of blood return reservoir 150 of cassette assembly 110. The vent bag tubing assembly 100 includes vent tubing 102 and a vent bag 104." (*Id.* at col. 19, ll. 23-26.)

7. Keller discloses that "[f]ollowing collection of the desired quantity of red blood cells, . . . the red blood cell reservoir 954 may be disconnected from the extracorporeal tubing circuit 10. A storage solution may then be added." (*Id.* at col. 54, ll. 45-52.)

8. Keller discloses that "[a]fter the storage solution has been added to the collected red blood cells in the RBC reservoir 954, selective filtering may be desired to remove white blood cells" (*id.* at col. 55, ll. 21-27.)

9. Keller discloses that "[i]f such leukoreduction is deemed appropriate, the red blood cell/storage solution mixture can be connected to a commercially available red cell filter/bag so that red blood cells are gravity transferred from the collection bag 954 through a filter and into a new storage bag" (*id.* at col. 55, ll. 30-34).

10. The Specification states that the "RBC collection tubing sub-assembly is a preconnected part of the disposable" (Spec. 15: 27-28).

11. The Specification states that the "red cell filter/bag assembly is preferably preconnected onto the disposable as shown in Figs. 1, 2A and 2C in accordance with the teachings of this invention, or may be added to previously existing disposable systems to form a preconnected disposable using commercially available filter/bag kits" (*id.* at 76: 13-16).

Principles of Law

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt,* 211 F.3d 1367, 1372 (Fed. Cir. 2000).

Analysis

Keller discloses an embodiment of its device in which its RBC reservoir 954 is connected to a commercially available red cell filter/bag so that the RBCs are leukoreduced by passage through the filter and into a new storage bag. Appellant argues that Keller's disclosure does not describe a leukoreduction filter and RBC storage bag "preconnected" to its device.

However, Appellant's Specification states that a "red cell filter/bag assembly . . . may be added to previously existing disposable systems to form a preconnected disposable using commercially available filter/bag kits" (FF 11). This embodiment of a "preconnected disposable" reasonably appears to be the same as Keller's description of adding a commercially available filter/bag assembly to its device. Keller does not state that a worker using its device would have to wait until after RBCs have been collected to attach the commercially available filter/bag assembly, and therefore reasonably appears to describe "preconnecting" the leukoreduction

filter and RBC storage bag to the rest of its product before using the combined product to collect leukoreduced RBCs.

Conclusions of Law

The Examiner did not err in finding that claim 1 reads on an embodiment disclosed by Keller.

OBVIOUSNESS BASED ON KELLER

Issue

The Examiner has rejected claim 2 as obvious in view of Keller. The Examiner finds that Keller discloses "an air removal bag (104) that is connected to the cassette assembly," rather than to the RBC storage bag as required by claim 2 (Answer 6). The Examiner concludes that it would have been obvious "to connect the air removal bag to the RBC storage bag to remove air therefrom, since it has been held that rearranging parts of an invention involves only routine skill in the art" (*id.*).

Appellant contends that Keller's vent bag is connected "to the top of the blood return reservoir 150 of cassette assembly 100," which is not a red blood cell storage bag (Appeal Br. 6). "Therefore, it is not a mere rearrangement of parts as the Examiner suggests. It would not be obvious for one skilled in the art to attach an air removal bag to a separate and distinct bag that is used to store leukoreduced red blood cells." (*Id.*).

The issue with respect to this rejection is: Did the Examiner err in concluding that Keller would have suggested an air removal bag interconnected to its red blood cell storage bag, as required by claim 2?

Principles of Law

A conclusion of obviousness requires showing that "there was an apparent reason to combine the known elements in the fashion claimed." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). "We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

Analysis

We will reverse the rejection of claim 2. While it may have required only routine skill to connect an air removal bag to the RBC storage bag of Keller's device, the Examiner has pointed to no evidence in the prior art or within the knowledge of the ordinarily skilled worker that would show recognition of a need to remove air from the RBC storage bag. The Examiner therefore has not shown that a person of ordinary skill in the art would have had an apparent reason to modify Keller's device as required by claim 2.

The Examiner also cited Keller's disclosure that the function of its vent bag could be carried out by "other integral passageways, integrated chambers [or] tubing loops" (Answer 9). Those alternatives, however, all carry out the same function as Keller's vent bag, which is to remove air from the cassette assembly, not the RBC storage bag. The Examiner has not shown that they would have suggested a bag for removing air from an RBC storage bag.

Conclusion of Law

The Examiner erred in concluding that Keller would have suggested an air removal bag interconnected to its red blood cell storage bag, as required by claim 2.

OBVIOUSNESS BASED ON KELLER AND MINSHALL

Issue

The Examiner has rejected claims 3 and 4 as obvious in view of Keller and Minshall. The Examiner finds that Keller does not disclose "the use of frangible connectors in the tubing between the leukoreduction filter and RBC collection bag" (Answer 7). The Examiner finds that Minshall teaches "a closed apheresis kit or circuit containing tubing and bags connected . . . [with] normally closed frangible connectors in the flow path of each portion to keep the circuit sterile" (*id.*). The Examiner concludes that it would have been obvious "to modify the tubing of Keller to include frangible connectors in the tubing between the filter and collection bag to keep the pathway sterile" (*id.*).

Appellant contends that "Minshall discloses a tubing connector which is a flexible plastic sleeve which joins two separate and distinct tubing pieces together" (Appeal Br. 7), not "a single tubing with a frangible connector interconnected between a leukoreduction filter and a red blood cell collection bag" (*id.*).

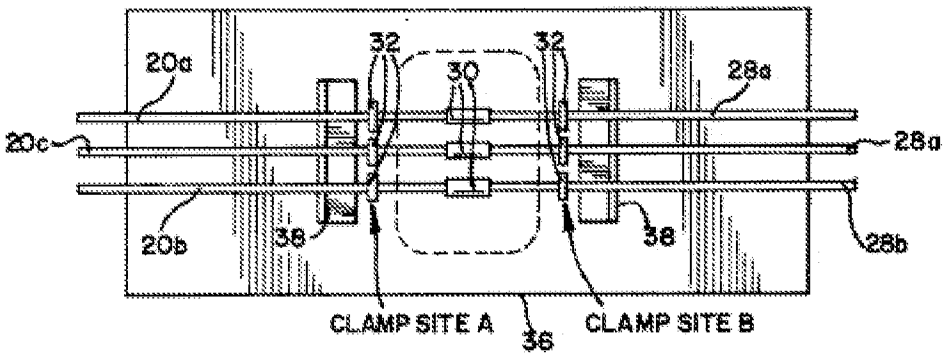
The issue with respect to this rejection is: Did the Examiner err in concluding that Minshall would have suggested modifying Keller's product to include a frangible connector in the tubing connecting its RBC collection bag and leukoreduction filter?

Findings of Fact

12. Minshall discloses a method of sterilizing a product having parts requiring different, incompatible methods of sterilization (Minshall, col. 2, ll. 25-33).

13. Minshall discloses that the two parts of the product can be separately sterilized prior to joining them together (*id.* at col. 2, ll. 41-59).

14. Minshall's Figure 6 is shown below:



The figure shows "product portions [being] joined by first isolating a terminal end portion of the tubing segments 20a-c and 28a-c from the remainder of the particular product portion" (*id.* at col. 6, ll. 18-20).

15. Minshall discloses that "[i]n the preferred embodiment, the terminal end portions of the tubings 20a and 28a are isolated from the remainder of the tubing and the product portions by removable plastic, radiation permeable slide claims 32. Alternatively, the end portions may be isolated by internal frangible closures." (*Id.* at col. 6, ll. 25-30.)

16. Minshall discloses that "the end segments of the tubings 20a-c and 28a-c are isolated by slide claims 32 prior to joinder. The sterile end covers . . . of each tubing segment are then removed and the ends of the tube

are inserted into the flexible plastic sleeve 30 and solvent sealed therewithin." (*Id.* at col. 7, ll. 20-25.)

17. Minshall discloses that, following joinder, the isolated parts of the tubing are mounted on a fixture 36 as shown in Figure 6 and exposed to radiation to sterilize them (*see id.* at col. 6, ll. 34-42; col. 7, ll. 26-40).

Analysis

Keller discloses an embodiment of its apparatus that includes a leukocyte reduction filter and RBC storage bag connected to its RBC collection bag, but does not disclose that the tubing connecting the RBC collection bag to the leukocyte reduction filter includes a frangible connector. The Examiner concludes that including a frangible connector would have been obvious based on Minshall's disclosure of using frangible connectors to isolate the end portions of two tubing segments before joining and irradiating them.

We agree with Appellant that the Examiner has not adequately explained why it would have been obvious to combine Minshall's frangible connectors with Keller's system. In particular, the Examiner has not provided any evidence to show that connecting a commercially available leukocyte reduction filter/RBC storage bag to Keller's system, as taught by Keller, would require joining tubes using frangible connectors, solvent-sealing within a plastic sleeve, and irradiating to sterilize, as taught by Minshall. Thus, the Examiner has not adequately shown that it would have been obvious to combine Minshall's method involving frangible connectors with Keller's apheresis apparatus.

Conclusion of Law

The Examiner erred in concluding that Minshall would have suggested modifying Keller's product to include a frangible connector in the tubing connecting its RBC collection bag and leukoreduction filter.

SUMMARY

We affirm the rejection of claims 1, 5, and 6 as anticipated by Keller but reverse the rejection of claims 2-4 as obvious in view of Keller or Keller and Minshall.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

dm

CARIDIAN BCT, INC.
MAIL STOP: 810 1F2
10811 WEST COLLINS AVE
LAKEWOOD, CO 80215